

EXHIBIT B

Jerry G. Blaivas, M.D.

1 UNITED STATES DISTRICT COURT
2 SOUTHERN DISTRICT OF WEST VIRGINIA
3 AT CHARLESTON
4 -----:
IN RE ETHICON, INC., PELVIC :
5 REPAIR SYSTEM PRODUCTS : MASTER FILE
LIABILITY LITIGATION : No. 2:12-MD-02327
6 -----:
:
7 THIS DOCUMENT RELATES TO : MDL 2327
ALL WAVE 3 CASES :
8 : JOSEPH R. GOODWIN
: US DISTRICT JUDGE

9 -----
10 - - -
11 August 29, 2016
12 - - -

13 DEPOSITION of JERRY G. BLAIVAS,
14 M.D., commencing at 12:00 p.m. on the above
15 date at Urocenter of New York, 445 East 77th
16 Street, New York, New York, before Marie Foley,
17 a Registered Merit Reporter, Certified Realtime
18 Reporter and Notary Public of the State of New
19 York.

20 - - -
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24

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<p style="text-align: right;">Page 14</p> <p>1 are not caused by the polypropylene 2 midurethral sling? 3 A. Yes. 4 Q. And it's fair to say that in 5 your clinical practice, there are times 6 that you diagnose women's complications as 7 being related to the polypropylene 8 midurethral sling that they have? 9 A. Yes. 10 Q. When a woman presents to you 11 with a complication that you then 12 determine after examination is caused by a 13 midurethral sling, what treatment options 14 do you offer to that woman? 15 A. Well, it depends what the 16 complication is. Generally, and these are 17 very -- you know, it depends what the 18 complication is. If it's clearly an 19 obstruction from the sling, and when there 20 is an obstruction that's what it usually 21 is, then my recommendation is that we 22 remove the entire suburethral portion of 23 the sling. 24 If the complication is a</p>	<p style="text-align: right;">Page 16</p> <p>1 woman's specific problems? 2 A. Of course. 3 Q. And would you say that you try 4 to treat the problems as conservatively as 5 possible, with the least amount of surgery 6 necessary to correct those problems? 7 A. No, I would say I try to be 8 appropriate. I mean, sometimes it's 9 appropriate to be conservative. Sometimes 10 it's appropriate to be radical, but I 11 discuss it with the patient. 12 Q. Okay. Now, in addition to your 13 clinical work and your clinical 14 experience, you also have done academic 15 work and published articles concerning 16 mesh and mesh complications, correct? 17 A. I have. 18 Q. And most recently you published 19 an article entitled "Safety Considerations 20 for Synthetic Sling Surgery" that was 21 published in the Nature Reviews of Urology 22 in 2015, correct? 23 A. Yes. 24 Q. And you were a co-author on that</p>
<p style="text-align: right;">Page 15</p> <p>1 fistula, then we remove all of the sling, 2 all of the sub -- all of the sling that's 3 in the vicinity of the urethra -- excuse 4 me, of the fistula and then repair the 5 fistula. 6 If it's pain, then it depends 7 where the pain is, and again I don't have 8 to go into the particulars, but sometimes 9 we just remove that portion that appears 10 to be related or causing the pain, but 11 sometimes we remove the entire mesh 'cause 12 I think the entire mesh is causing the 13 pain. 14 If it's overactive bladder 15 symptoms, we -- if it's due to urethral 16 obstruction, we remove the suburethral 17 portion. If we're not -- if it seems like 18 it's in the wall of the bladder but -- or 19 through the wall of the bladder, then we 20 remove all of the sling on that side and 21 sometimes the entire sling. 22 Q. Is it fair to say based on what 23 you've just told me that the treatment 24 options that you offer are tailored to a</p>	<p style="text-align: right;">Page 17</p> <p>1 with eight other individuals, correct? 2 A. Yes. 3 Q. Can you tell me, first of all, 4 how this article came to be? 5 A. Well, Nature Reviews in Urology 6 is a highly respected peer review journal, 7 and they, for their reviews they actually 8 solicit authors. I don't believe you can 9 just submit. I'm not sure of that. 10 But they asked me to do a review 11 article, and they told me right up front 12 that just because I agreed to do it, it 13 did not mean that it would be automatically 14 accepted. 15 Q. Now, can you tell us what a 16 review article is? 17 A. A review article is, there are 18 lots of different types, but basically 19 it's a compilation of many and sometimes 20 all of the articles in the peer review 21 literature about a certain topic. And 22 then, so the first thing that you do is 23 you -- is you do a literature search and 24 you identify the articles and then you use</p>

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<p style="text-align: right;">Page 18</p> <p>1 search criteria to eliminate certain 2 articles and then you analyze them based 3 on whatever methodology you choose. 4 Q. So, let me discuss, you were 5 approached by Nature and asked to conduct 6 a review on the literature available 7 concerning synthetic sling surgery, 8 correct? 9 A. Yes. 10 Q. And, I see that we mentioned you 11 have a number of other authors here. 12 Are those authors that you asked 13 to help you with this, or are those 14 authors that Nature assigned to this 15 project? 16 A. No, I got to select my team. 17 Q. Can you tell me how you went 18 about selecting the team? 19 A. Sure. Well, okay, so, two of 20 the co-authors, Robert Bendavid and 21 Vladimir Latovlev, L-A-T-O-V-L-E-V, are 22 recognized authorities in the field, and I 23 asked them if they would be willing to 24 help me with this.</p>	<p style="text-align: right;">Page 20</p> <p>1 why they selected you or asked you to 2 write this article over others? 3 A. Well, yes, they had heard -- 4 one, they heard about me, they knew of me 5 and they asked around and they asked who 6 would be a good person to do it, and I 7 believe someone had seen me participate in 8 a debate at the annual meeting of the 9 American Urologic Association. 10 Q. Was there any kind of 11 preconceived outcome that anyone had 12 discussed with you of what they expected 13 your research to show or not show? 14 A. No. 15 Q. Now, this article that you did, 16 a review article, does not contain all of 17 the articles available in the medical 18 literature that reference or concern 19 midurethral slings, correct? 20 A. Correct. 21 Q. How did you and your co-authors 22 determine and choose the articles that you 23 relied on for this particular piece? 24 A. Well, two ways. One, and I'm</p>
<p style="text-align: right;">Page 19</p> <p>1 One of them, Roger Purohit, 2 P-U-R-O-H-I-T, is my partner, so we 3 operate together and he has a considerable 4 amount of clinical experience. And then 5 Matt Benden and Gabriel Mekel, M-E-K-E-L, 6 and Michael Stern and Mubashir Billah, 7 B-I-L-L-A-H, and I'll have to spell the 8 other ones, K-O-L-A is the first name and 9 it's O-L-U-G-B-A-D-E, were all students 10 that -- well, actually, Dr. Mekel was 11 doing a fellowship with me and the others 12 are either medical students, or are all 13 medical students. 14 Q. Okay. When did Nature approach 15 you about authoring a review on synthetic 16 sling surgery? 17 A. It was some time after May of, I 18 guess, 20 -- I don't know if it was 2013 19 or -- probably -- or 2014. I can't 20 remember. 21 Q. Okay. 22 A. But it was after the American 23 Urologic Association national meeting. 24 Q. Did anyone from Nature tell you</p>	<p style="text-align: right;">Page 21</p> <p>1 sorry, I don't have all the details in my 2 memory, but there was an article 3 published -- there was another review 4 article that I thought was timely that did 5 a review up to a certain date and then 6 we -- I just decided to do it from about 7 that time to the what was then current, 8 which was 2014. And I can tell you in a 9 minute what the dates were. 10 Q. Sure. 11 (Pause.) 12 A. So, it was from 2007 to 2014. 13 Excuse me, that was for the 14 clinical review, okay. Dr. Latovlev 15 independently reviewed the pathology which 16 went back many years before that. 17 Q. One of the things that I want to 18 talk to you about today is the conclusions 19 that you reached concerning the 20 complications and the complication rates 21 associated with midurethral slings. 22 Would that be included in the 23 clinical review that you just mentioned? 24 A. Yes.</p>

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<p style="text-align: right;">Page 22</p> <p>1 Q. So, you and your co-authors 2 chose articles written from 2007 to 2014, 3 and I think what you mentioned to me 4 before was that there's certain search 5 criteria that you use when conducting your 6 literature search to determine what 7 articles would be included in a review 8 article; is that right? 9 A. Yes. 10 Q. And can you tell me what the 11 search criteria that you and your 12 co-authors were? 13 A. It's a long list. Shall I read 14 it to you? 15 Q. Sure. 16 A. Okay. So, the search combined 17 the terms, and some of these are just 18 spelling things. So, there was 19 midurethral slings where "mid" and 20 "urethral" are two words; midurethral 21 slings where "midurethral" is one word; 22 suburethral sling, urethral sling, 23 midurethral slings with a plural, both 24 words again with a plural. All of the</p>	<p style="text-align: right;">Page 24</p> <p>1 we did on the clinical end. 2 Q. Okay. And that sounds like 3 quite a number of search terms; is that 4 right? 5 A. Yes. 6 Q. Why did you have so many search 7 terms? 8 A. 'Cause we didn't want to miss 9 any articles, and what we did is we would 10 look up -- we started with less search 11 terms and as we read articles, we would 12 see synonyms or new words and then we 13 would add that to the search term. 14 Q. Did you limit the types of 15 articles you were looking at? For 16 example, did you only look at randomized 17 control trials or only look at 18 meta-analyses or only look at case 19 studies? 20 A. No, we did not limit it. 21 Q. Is it fair to say that you were 22 trying to get as big a cross-section or as 23 big a representation of all of the 24 articles out there and kind of gather them</p>
<p style="text-align: right;">Page 23</p> <p>1 words that I just said also in plural. 2 Follow-up study, other than all of those 3 terms and follow-up study. 4 Also, we used free text searches 5 including the terms urinary 6 incontinence -- excuse me, TVT, tension 7 free vaginal tape, tension free vaginal 8 sling, transobturator tape, transobturator 9 sling, TVT-Obturator, TVT-O, TVT Secure, 10 Minarc, that's M-I-N-A-R-C, Abbrevio, 11 A-B-B-R-E-V-I-O, TOT, suprapubic arc 12 sling, Sparc, S-P-A-R-C, sling, 13 intravaginal slingplasty, IVS sling, RAZ, 14 R-A-Z, sling, Uratape, that's 15 U-R-A-T-A-P-E, ObTape, O-B-T-A-P-E, 16 prepubic sling, prepubic TVT, prepubic 17 tape, Pelvilace, P-E-L-V-I-L-A-C-E, 18 ureter, Aris, A-R-I-S, In-Fast, 19 I-N-F-A-S-T, Monarc I-STOP, urethral 20 reconstruction, urethral vaginal fistula, 21 other spelling of ObTape, Gore-Tex sling, 22 silastic sling, Mersilene sling, Marlex 23 sling, vesicovaginal fistula, Bioarc. And 24 then -- yeah, so that was the search that</p>	<p style="text-align: right;">Page 25</p> <p>1 up before you got started with this 2 process? 3 A. Yes. I just remembered there 4 was actually, there was one exclusion 5 criteria that we used. If an article by 6 the same authors seemed to include the 7 same patients in a different study, we 8 would have used the most -- either the 9 most recent one or the most appropriate 10 one. We tried not to count the same 11 patients twice. 12 Q. Okay. 13 A. So if one author had a 14 patient -- had a study that showed the 15 patients at one year, five years, 10 16 years, 15 years and 20 years, and they had 17 complications, we wouldn't count the 18 complications five times. We'd only count 19 the complications once. 20 Q. Okay. Is it fair to say that 21 you were attempting to count each patient 22 one time and not duplicate those patients 23 or those complications in your analysis at 24 all?</p>

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<p>1 A. Exactly.</p> <p>2 Q. And the method that you used to</p> <p>3 do that by only using one article from a</p> <p>4 series, is that a standard acceptable way</p> <p>5 of achieving that goal when doing medical</p> <p>6 or scientific research?</p> <p>7 A. You know, I don't know.</p> <p>8 Q. Tell me why you thought that it</p> <p>9 was an appropriate way to achieve that</p> <p>10 result.</p> <p>11 A. Because I wanted to be sure on</p> <p>12 the one hand that we captured every</p> <p>13 complication, but on the other hand we</p> <p>14 didn't count anybody twice 'cause we were</p> <p>15 looking to get as precise a number for</p> <p>16 both -- for complications as we could. We</p> <p>17 didn't want to overestimate; we didn't</p> <p>18 want to underestimate.</p> <p>19 Q. Okay. And that's for the</p> <p>20 clinical portion, and clinically you</p> <p>21 looked at both the safety of the product,</p> <p>22 correct, the complications?</p> <p>23 A. Yes.</p> <p>24 Q. And you also looked at the</p>	<p>1 dealt with high rates of complications?</p> <p>2 A. No.</p> <p>3 Q. Did you only look for articles</p> <p>4 that reported low rates of complications?</p> <p>5 A. No. We intend -- to the best of</p> <p>6 our ability, we picked every article in</p> <p>7 the literature in that time period.</p> <p>8 Q. And that are articles that</p> <p>9 reflected some lower rates of</p> <p>10 complications, correct?</p> <p>11 A. Of course.</p> <p>12 Q. And articles that reflected</p> <p>13 higher rates of complication, correct?</p> <p>14 A. Yes.</p> <p>15 Q. And fair to say it included case</p> <p>16 studies?</p> <p>17 A. Yes, it did.</p> <p>18 Q. It included randomized control</p> <p>19 trials?</p> <p>20 A. Yes.</p> <p>21 Q. It included meta-analyses?</p> <p>22 A. Yes.</p> <p>23 Q. Is there anything at all that</p> <p>24 you or your co-authors did to limit or</p>
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<p>1 efficacy of the product, correct?</p> <p>2 A. Yes.</p> <p>3 Q. Was there different criteria</p> <p>4 that you looked at for articles relating</p> <p>5 to efficacy?</p> <p>6 A. Yes. For articles for efficacy</p> <p>7 we only included those articles that</p> <p>8 measured efficacy, that had appropriate</p> <p>9 follow-up, and we did have criteria for</p> <p>10 that.</p> <p>11 Q. Is that different from -- it</p> <p>12 sounds like you had more exclusion</p> <p>13 criteria for the efficacy articles than</p> <p>14 you did the complication/safety articles;</p> <p>15 is that right?</p> <p>16 A. Yes.</p> <p>17 Q. Is there anything else that you</p> <p>18 excluded beyond, from your literature</p> <p>19 search, beyond the subsequent articles or</p> <p>20 the multi-reported cases?</p> <p>21 A. Yes. The only other exclusion</p> <p>22 was non-human subjects.</p> <p>23 Q. Did you in any way cherry pick</p> <p>24 or look only for reports or articles that</p>	<p>1 exclude certain articles or certain</p> <p>2 findings in articles that would otherwise</p> <p>3 have been encompassed in your search</p> <p>4 terms?</p> <p>5 A. Only for the efficacy studies.</p> <p>6 Q. Okay. Now --</p> <p>7 A. And that -- but those were a</p> <p>8 search term, so we -- so I guess the</p> <p>9 answer is no, we did not. Okay.</p> <p>10 Q. Now, could somebody look at what</p> <p>11 you've reported in Table 1 relating to the</p> <p>12 efficacy issues and extrapolate in any way</p> <p>13 what you did there and apply it to the</p> <p>14 complication tables that you reflected in</p> <p>15 Table 2, 3, 4 and 5?</p> <p>16 A. No, you couldn't because they</p> <p>17 didn't apply -- none of these -- well,</p> <p>18 most of these studies did not have any</p> <p>19 scientifically valid prospective way of</p> <p>20 looking at complications. This was just</p> <p>21 for efficacy.</p> <p>22 Q. Is there any way that someone</p> <p>23 could --</p> <p>24 MS. FITZPATRICK: Let me ask it</p>

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<p>1 a different way.</p> <p>2 Q. Is it correct that there are</p> <p>3 articles that you considered for your</p> <p>4 safety considerations or complication</p> <p>5 rates that are not reflected in the table</p> <p>6 concerning efficacy?</p> <p>7 A. Probably not because we would</p> <p>8 always -- no, because we would -- we</p> <p>9 would -- if there was even one</p> <p>10 complication, we would -- we would have</p> <p>11 included it.</p> <p>12 Q. But just because you had it, and</p> <p>13 I think what you're telling me is all of</p> <p>14 your efficacy articles were included in</p> <p>15 your complication analysis, and I'm</p> <p>16 actually asking the opposite.</p> <p>17 Were all of the articles that</p> <p>18 you considered for the complication part</p> <p>19 all used also to look at efficacy?</p> <p>20 A. No.</p> <p>21 Q. So you can't say that simply</p> <p>22 because something isn't on the Table 1</p> <p>23 that you didn't rely on it, use it,</p> <p>24 conclude anything about it or consider it</p>	<p>1 Q. And you've also been editor of a</p> <p>2 journal that is a peer review journal,</p> <p>3 correct?</p> <p>4 A. Yes.</p> <p>5 Q. Can you tell me generally in the</p> <p>6 medical and scientific community how</p> <p>7 individuals get selected as peer</p> <p>8 reviewers?</p> <p>9 A. Sure. They get selected by a</p> <p>10 process of usually by a committee of</p> <p>11 experts that picks other experts that they</p> <p>12 think contribute to the peer review</p> <p>13 process. So they have to show -- they</p> <p>14 have to be held in high regard as experts</p> <p>15 that can give a fair and unbiased</p> <p>16 appraisal of submissions.</p> <p>17 Q. Do you know of any peer review</p> <p>18 publication that has considered the</p> <p>19 opinions of attorneys from medical device</p> <p>20 manufacturers as part of peer review</p> <p>21 process?</p> <p>22 A. No, I do not.</p> <p>23 Q. Why aren't attorneys for medical</p> <p>24 device manufacturers qualified to serve as</p>
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<p>1 as part of your safety considerations and</p> <p>2 complication considerations; is that</p> <p>3 right?</p> <p>4 A. To the contrary; we would have</p> <p>5 used it.</p> <p>6 Q. Okay. Now, this article went</p> <p>7 through the peer review process, correct?</p> <p>8 A. Very much so.</p> <p>9 Q. Can you tell me what you mean by</p> <p>10 that?</p> <p>11 A. Well, the peer review process</p> <p>12 itself is designed to insure that the</p> <p>13 highest standards of scientific</p> <p>14 methodology were used in the paper and</p> <p>15 very specifically that the results and the</p> <p>16 conclusions follow from the methodology;</p> <p>17 i.e. that the conclusions follow from the</p> <p>18 methods.</p> <p>19 Q. Is there anything that was</p> <p>20 different about the Nature peer --</p> <p>21 MS. FITZPATRICK: Strike that.</p> <p>22 Q. You've worked as a peer reviewer</p> <p>23 before, correct, for other journals?</p> <p>24 A. Yes.</p>	<p>1 peer reviewers for a medical journal?</p> <p>2 A. Well, the most obvious reason is</p> <p>3 that their opinions were likely to be</p> <p>4 biased or that they have a major conflict</p> <p>5 of interest and they don't fulfill our</p> <p>6 criteria for being an expert. They're</p> <p>7 lawyers; they're not experts in</p> <p>8 scientific research.</p> <p>9 Q. Is it fair to say that the peer</p> <p>10 review process is designed to have</p> <p>11 neutral, objective, experienced</p> <p>12 individuals assessing the methodology and</p> <p>13 the conclusions that are reached in</p> <p>14 medical and scientific journals?</p> <p>15 A. Of course.</p> <p>16 Q. That process is designed to</p> <p>17 insure that the methodology that is used</p> <p>18 is something that is recognized and</p> <p>19 acceptable in the medical and scientific</p> <p>20 community, correct?</p> <p>21 A. Yes.</p> <p>22 Q. In your experience as both a</p> <p>23 peer reviewer and as an editor of a peer</p> <p>24 review journal, what happens in the</p>

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<p style="text-align: right;">Page 34</p> <p>1 process if an article is presented that 2 does not use established accepted 3 methodology in the scientific and medical 4 community? 5 A. Well, as a general rule, it's 6 rejected. On rare occasions, someone 7 comes up with such a novel approach that 8 even though that it wasn't known before, 9 it might become -- it might be acceptable. 10 Q. Do you believe that the peer 11 review -- let me ask you this. 12 Tell me about the peer review 13 process that you went through for your 14 Nature article. 15 A. This was the most rigorous peer 16 review that I've ever been part of. I 17 mean, we -- this article took more time 18 and more effort than any article I've ever 19 written, and I, you know, I've done 20 hundreds and hundreds. So it was a very 21 labor intense project. We read all of the 22 articles, and then when we wrote the 23 articles, we submitted it and they had a 24 number of questions, concerns, suggested</p>	<p style="text-align: right;">Page 36</p> <p>1 methodology in connection with that 2 article at any time prior to its 3 publication? 4 A. Well, they asked questions about 5 it in the review process, but I don't -- 6 but afterwards, no, I don't -- I'm not 7 aware of anybody questioning it. 8 Q. And are you comfortable that the 9 Nature Review Urology looked closely at 10 the methodology that you and your 11 co-authors used to reach the conclusions 12 that you did in that review paper? 13 A. I'm quite confident of that. 14 Q. We're going to talk in a little 15 bit specific about some of the conclusions 16 in that article and I'm going to ask you 17 more specifically how you reached the 18 conclusions that you did. 19 But, in addition to the 20 conclusions that you reached in that 21 article, you also rely on your clinical 22 experience for an independent basis of 23 your TVT-Exact report, correct? 24 A. Yes.</p>
<p style="text-align: right;">Page 35</p> <p>1 revisions and it went back and forth a 2 number of times to be sure that we -- that 3 our -- to be sure, quite honestly, that 4 our, as I mentioned a few minutes ago is 5 that our results and conclusions were 6 clearly supported by the methodology and 7 that they were scientifically sound. 8 Q. Do you believe, Doctor, that the 9 fact that your article in Nature Review 10 survived the peer review process 11 establishes that the methodology that you 12 and your co-authors used in that, in 13 drafting that article, was scientifically 14 reliable? 15 A. I do. 16 Q. Would it be widely considered in 17 your medical community that an article 18 such as yours that has gone through such a 19 rigorous peer review process has 20 demonstrated appropriate medical and 21 scientific methodology? 22 A. Yes. 23 Q. Has anybody in the medical 24 community or at Nature questioned your</p>	<p style="text-align: right;">Page 37</p> <p>1 Q. And including those portions 2 that overlap with the other polypropylene 3 midurethral sling products that you've 4 offered reports on, correct? 5 A. Yes. 6 Q. In addition to your Nature 7 article, in addition to your clinical 8 experience, did you also rely on 9 peer-reviewed literature which was 10 identified both in the footnotes of your 11 report and then in the reliance list that 12 you provided with that report? 13 A. I did. 14 Q. In selecting that peer-reviewed 15 literature for inclusion in your report or 16 your reliance list, were there any 17 articles that you just dismissed out of 18 hand and refused to consider when reaching 19 the opinions that you have in this case? 20 A. I don't dismiss them out of 21 hand. I mean, there's some that I don't 22 agree with the methodology. 23 I mean, are you asking in 24 general?</p>

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<p>1 went about calculating the percentage of 2 patients who have a potential complication 3 based on what's available in the medical 4 literature; is that right?</p> <p>5 A. Yes.</p> <p>6 Q. Now, the next column is 7 "Incident mean range."</p> <p>8 That's the second way that you 9 went about also checking on the reports of 10 complications and the incidence of 11 complications, correct?</p> <p>12 A. Yes.</p> <p>13 Q. Can you explain to me how the 14 methodology for reaching the incidence 15 differs from the methodology used for 16 reaching the complications?</p> <p>17 A. Sure. In the first case, we 18 counted every single patient, every single 19 patient was counted once. In the 20 incidence, where it says "Incidence mean 21 and range," those -- that we only 22 considered series of patients. So that 23 doesn't include any of the patients 24 with -- that were case reports. It</p>	<p>1 that you had and the mean.</p> <p>2 How do you account for that?</p> <p>3 A. Because in the series, they may 4 not have mentioned a certain complication. 5 So for example, if you're looking at that 6 same column, if you look at neurologic 7 symptoms within six weeks, in the middle 8 column we counted every single patient 9 where they mentioned it. Now, it looks 10 like there were only 42 patients in that 11 particular group where they said these 12 patients had these complications. Whereas 13 in the other article, they could have had 14 a paper with a thousand patients in it, 15 but they didn't even mention whether or 16 not there was a neurologic complication, 17 so we couldn't count that.</p> <p>18 Q. And in any event, let me look at 19 the range. So, tell me what the range is.</p> <p>20 A. Well, the range is -- describes 21 what the minimum complication rate was in 22 one series and the maximum in another -- 23 in other series, and the reason that we 24 did that is one of the critiques that you</p>
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<p>1 doesn't include any of the patients, for 2 example, that were just a paper on 3 complications.</p> <p>4 So the numbers in these two 5 columns, even though they both represent 6 means or averages, the numbers could be 7 very different because they're different 8 populations of papers.</p> <p>9 Q. So, this was the way that you 10 and your co-authors went about presenting 11 the full gamut of information based on two 12 statistical analyses, correct?</p> <p>13 A. Exactly.</p> <p>14 Q. And you reported on both the 15 complications and the incidence without 16 consideration to what was higher or lower? 17 You made sure everything was reported 18 here, correct?</p> <p>19 A. Exactly.</p> <p>20 Q. In some of these, the numbers 21 are fairly comparable, right?</p> <p>22 A. Yes.</p> <p>23 Q. And in some of them there's some 24 divergence in the percentage of patients</p>	<p>1 might apply to this kind of scientific 2 literature is, well, if you just do an 3 average -- if you just do an average, it 4 doesn't tell you about the difference 5 between perhaps, this is a perhaps, people 6 that are really expert surgeons might get 7 a zero complication rate and novices 8 might, you know, get a 15 percent 9 complication rates.</p> <p>10 So this gives you the range of 11 what you might expect with the same 12 surgeon or groups of surgeons doing the 13 operation.</p> <p>14 Q. In looking at both your 15 percentage of patients, as well as the 16 mean that you have reported in this 17 article, all of those fall within below 18 the highest reported incident rate on the 19 range; is that right?</p> <p>20 A. Sure. That makes sense.</p> <p>21 Q. So, does that reflect that your 22 article is not reporting the highest 23 possible rates of complications associated 24 with any of these complications?</p>

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1 them and they have de novo overactive
 2 bladder and you treat them, X number would
 3 get better. So I don't have the exact
 4 number, but we picked the number of de
 5 novo overactive bladder patients and then
 6 we took a percentage of that, of patients
 7 that are likely to be refractory, and when
 8 you add all those numbers up -- then we
 9 added a couple of -- there were a few
 10 things like bowel injuries and fistulas
 11 that are very rare, but we added in a
 12 number of that and added all of those up,
 13 the methodology, it's in the paper
 14 someplace.
 15 Q. And that's the same methodology?
 16 A. Yeah.
 17 Q. Just so I understand, if I'm
 18 looking at box 1 on page 8 of your
 19 article.
 20 A. Okay.
 21 Q. It says: "Complications
 22 requiring surgery."
 23 Is this the list of
 24 complications that you would consider a

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1 serious complication for the purposes of
 2 calculating that 15.3 percent number?
 3 A. Yes.
 4 Q. Is it fair to say that, or am I
 5 accurate in saying that that list of
 6 complications, plus the number of sling
 7 failures, the percentage of women whose
 8 slings simply don't work for them, you
 9 calculated that total --
 10 A. No, no, that's in there. The
 11 recurrent and/or persistent stress
 12 incontinence.
 13 Q. Okay.
 14 A. That number is -- that's where
 15 the number comes from.
 16 Q. Okay. Thank you for clarifying
 17 that.
 18 So, when you say there's a total
 19 incidence of serious complications is 15.3
 20 percent, is it accurate to say that's the
 21 calculation of the overall risk to a woman
 22 that one of these things could happen to
 23 her if she has a polypropylene midurethral
 24 sling implanted?

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1 A. I would say it another way.
 2 That there's a, I believe, at least a 15
 3 percent chance of having a negative
 4 outcome from the sling, from putting the
 5 sling in.
 6 Q. And the negative outcomes would
 7 be one of those things that you have
 8 identified in Box 1?
 9 A. Yes.
 10 Q. But it's not your testimony, for
 11 example, that 15.3 percent of women who
 12 have a midurethral sling will have chronic
 13 pain?
 14 A. No.
 15 Q. Or that 15.3 percent will have a
 16 urethral obstruction, correct?
 17 A. Correct.
 18 Q. It's just the overall chances of
 19 having one of these negative outcomes?
 20 A. Yes.
 21 Q. Now, going back in time, you
 22 published this article in late 2015; is
 23 that right?
 24 A. Yes.

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1 Q. And it was based on medical
 2 records 2007 through 2014; is that right?
 3 A. Yes.
 4 Q. And do you recall that in the
 5 summer of 2014, you testified in front of
 6 Judge Goodwin in the Southern District of
 7 West Virginia in a case involving Mrs. Joe
 8 Husky; is that right?
 9 A. I have a remote memory of it,
 10 yes.
 11 Q. Well, I put you on the stand,
 12 so.
 13 A. No, I did it.
 14 Q. So I know that you did it.
 15 And at that time, you had not
 16 done the statistical analyses and this
 17 analysis that's reflected in your Nature
 18 article, correct?
 19 A. I'm sorry, what was the date?
 20 Q. Summer of 2014.
 21 A. Correct.
 22 Q. So, since you testified in Mrs.
 23 Husky's case in the summer of 2014, have
 24 you done additional work that you rely on

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<p style="text-align: right;">Page 70</p> <p>1 as the basis for your current opinions</p> <p>2 reflected in this expert report on the</p> <p>3 incidence of individual complications rate</p> <p>4 and the overall complication rate?</p> <p>5 A. Well, of course. That's what</p> <p>6 this paper is.</p> <p>7 Q. And this information wasn't</p> <p>8 available to you and you had not done this</p> <p>9 analysis at the time of Mrs. Husky's</p> <p>10 trial, correct?</p> <p>11 A. Correct.</p> <p>12 Q. Ethicon has made a statement</p> <p>13 that you may not -- I'm going to quote</p> <p>14 you: "Dr. Blaivas may not, quote, merely</p> <p>15 a year later, quote, purport to be certain</p> <p>16 about TVT complication rates."</p> <p>17 Can you tell me why you can be</p> <p>18 certain about complication rates in August</p> <p>19 of 2015 when you couldn't be certain about</p> <p>20 complication rates in the summer of 2014?</p> <p>21 A. Because we did such an</p> <p>22 exhaustive search of the literature and</p> <p>23 this is our best estimate of the minimum</p> <p>24 complication rate. I emphasize that.</p>	<p style="text-align: right;">Page 72</p> <p>1 A. No. I think if anything, it</p> <p>2 errs on the lower complication rate.</p> <p>3 Q. And is that reflected in the</p> <p>4 fact that both the complication percentage</p> <p>5 and the incidence that you report out are</p> <p>6 lower than the highest rates that you saw</p> <p>7 in the research that you did?</p> <p>8 A. Well, in part, but not --</p> <p>9 MS. FITZPATRICK: Take a break.</p> <p>10 (Discussion held off the record.)</p> <p>11 MS. FITZPATRICK: Can you read</p> <p>12 back the question and answer?</p> <p>13 (The requested portion of the</p> <p>14 record was read by the Court Reporter.)</p> <p>15 A. Yeah, because we don't expect it</p> <p>16 to be the highest rate reported, but we</p> <p>17 know that the studies, that the majority</p> <p>18 of the studies don't follow the patient</p> <p>19 long enough to account for all the</p> <p>20 complications and that there's no registry</p> <p>21 and there isn't -- and they don't -- there</p> <p>22 isn't a methodology to specifically look</p> <p>23 for complications. So because of those</p> <p>24 three things alone, it's very likely that</p>
<p style="text-align: right;">Page 71</p> <p>1 Q. And when you call it an</p> <p>2 estimate, it's an estimate that is based</p> <p>3 on two different scientifically reliable</p> <p>4 means for calculating the rates of</p> <p>5 complication; is that right?</p> <p>6 A. Yes.</p> <p>7 Q. And those are the ones that are</p> <p>8 reflected in Tables 2, 3, 4 and 5 of the</p> <p>9 report?</p> <p>10 A. I'll take your word for it.</p> <p>11 Yes.</p> <p>12 Q. I just want to make sure that</p> <p>13 I'm right.</p> <p>14 A. Okay.</p> <p>15 Q. Dr. Blaivas, do you believe that</p> <p>16 the conclusions that you reached in your</p> <p>17 report and in your Nature article assume</p> <p>18 the worst case scenario?</p> <p>19 A. No. As I said, I think it</p> <p>20 assumes the best case scenario.</p> <p>21 Q. And do you believe that it errs</p> <p>22 on the side of opining as to a higher</p> <p>23 complication rate to better protect a</p> <p>24 patient?</p>	<p style="text-align: right;">Page 73</p> <p>1 the complication rate that we reported is</p> <p>2 an underestimate of the real number of the</p> <p>3 complications.</p> <p>4 Q. Now, Ethicon claims that your</p> <p>5 Review article cherry-picked data in</p> <p>6 failing to take into account long-term</p> <p>7 studies finding TVT complication rates to</p> <p>8 be much lower. And they then refer to the</p> <p>9 articles that are identified in Table 1</p> <p>10 and states that at Table 1 of the article,</p> <p>11 the authors collected 11 studies</p> <p>12 purportedly meeting the criteria for</p> <p>13 inclusion.</p> <p>14 Do those articles have to do</p> <p>15 with efficacy and your conclusions about</p> <p>16 efficacy, or do they have to do with the</p> <p>17 overall rates of complications?</p> <p>18 A. The methodology was primarily</p> <p>19 geared towards efficacy.</p> <p>20 Q. So, is it accurate to say that</p> <p>21 simply because something was not included</p> <p>22 in Table 1, it is incorrect for Ethicon to</p> <p>23 say that you did not take into account</p> <p>24 long-term studies that find TVT</p>

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<p style="text-align: right;">Page 74</p> <p>1 complication rates to be lower?</p> <p>2 A. I'm sorry, there was a couple of</p> <p>3 negatives in there. I'm not sure about</p> <p>4 that.</p> <p>5 Q. Okay. Ethicon attempts to use</p> <p>6 the fact that there were certain articles</p> <p>7 that you did not consider for efficacy as</p> <p>8 evidence that you did not use those</p> <p>9 articles for consideration of safety.</p> <p>10 Is that accurate?</p> <p>11 A. It's not accurate.</p> <p>12 Q. Why not?</p> <p>13 A. Because one thing I already</p> <p>14 alluded to is that we only counted the</p> <p>15 patients once. So if a patient -- I mean,</p> <p>16 for example, I know one of the articles in</p> <p>17 there -- when I say "know," let me just</p> <p>18 double check.</p> <p>19 (Pause.)</p> <p>20 For example, the Nielson</p> <p>21 article -- no, this doesn't answer your</p> <p>22 question. Excuse me.</p> <p>23 The answer is "no" because some</p> <p>24 of the papers that they cited in that --</p>	<p style="text-align: right;">Page 76</p> <p>1 A. I don't believe so.</p> <p>2 Q. Now, defendants claim that your</p> <p>3 opinion that the TVT has a minimal</p> <p>4 complication rate takes into account</p> <p>5 prolapse devices.</p> <p>6 Did you look at articles or</p> <p>7 consider statistics on prolapse devices</p> <p>8 when reaching your complication rate in</p> <p>9 this paper?</p> <p>10 A. We did not look at -- if a paper</p> <p>11 had -- it's possible that some of the</p> <p>12 papers had patients with both prolapse and</p> <p>13 slings, but in the review process, we</p> <p>14 would have made our best effort to only</p> <p>15 include those patients that had to do with</p> <p>16 sling -- that where the complication was</p> <p>17 from a sling.</p> <p>18 Q. Is it fair to say that Ethicon's</p> <p>19 claim that you included prolapse devices</p> <p>20 in calculating your complication rate is</p> <p>21 untrue?</p> <p>22 A. To the best of our ability to</p> <p>23 make the distinction, it's untrue.</p> <p>24 MS. FITZPATRICK: Can we go off</p>
<p style="text-align: right;">Page 75</p> <p>1 in that deposition or, I think it was a</p> <p>2 deposition, were papers that were</p> <p>3 duplicate, so they used the same patients</p> <p>4 twice, and I already testified that when</p> <p>5 that happens, we only counted the</p> <p>6 complication once.</p> <p>7 And the second thing is that if</p> <p>8 an article did not mention a complication,</p> <p>9 that it wasn't included. They didn't say</p> <p>10 that they even looked for it.</p> <p>11 And then thirdly, I do remember,</p> <p>12 again I don't remember the specifics, but</p> <p>13 there was one or two articles that didn't</p> <p>14 come up in our search, and I don't know,</p> <p>15 you know, we did a very methodical search,</p> <p>16 but we searched thousands of papers and</p> <p>17 it's not unexpected that one or two</p> <p>18 wouldn't come up with a search.</p> <p>19 Q. And is that something that</p> <p>20 routinely happens in peer-reviewed</p> <p>21 articles?</p> <p>22 A. Sure.</p> <p>23 Q. Does it call into question the</p> <p>24 reliability of a peer review article?</p>	<p style="text-align: right;">Page 77</p> <p>1 the record for a second?</p> <p>2 (Discussion held off the record.)</p> <p>3 BY MS. FITZPATRICK:</p> <p>4 Q. Dr. Blaivas, you participated in</p> <p>5 the committee at the AUA that considered</p> <p>6 the safety and efficacy of midurethral</p> <p>7 slings, correct?</p> <p>8 A. Yes.</p> <p>9 Q. Can you tell me what you did in</p> <p>10 that respect, what you personally did?</p> <p>11 A. Well, we all -- it was a</p> <p>12 complicated process, similar to what I</p> <p>13 testified before. We did a literature</p> <p>14 search. We had inclusion criteria. We</p> <p>15 selected papers that had to do with the</p> <p>16 surgical management of urinary</p> <p>17 incontinence in women. We selected the</p> <p>18 papers and we tabulated the data on safety</p> <p>19 and efficacy, very similar to what we did</p> <p>20 in the Nature Review article for that</p> <p>21 column in the right where we looked at the</p> <p>22 incidence and the range. And we did that</p> <p>23 for all of the known treatments to stress</p> <p>24 incontinence at the time, surgical</p>